

**Maryland Board of Pharmacy  
Public Board Meeting Minutes  
June 16, 2004**

**Attendance**

**Officers:** Melvin Rubin, President; Raymond Love, Treasurer; Jeanne Furman, Secretary

**Commissioners:** John Balch, Ramona McCarthy-Hawkins, Christiaan Blake, Mark Levi, Mayer Handelman, Donald Taylor

**Absent:** William Johnson, Sr., Donald Yee, and Joseph DeMino

**Staff:** LaVerne G. Naesea, Executive Director; Linda Bethman, Staff Attorney, James Slade, Legislative Officer; Shirley Costley, Licensing Officer; Joan Lawrence, Public Information & Education Officer; Tamarra Banks, Management Information Services Officer

**Guests:** Gil Genn, M.A.C.D.S., Gil Cohen, PEAC, Steve Riggins, CVS Pharmacy, and Samantha Sin, University of Maryland Pharmacy Student; Megan Dillard, Governor's Summer Intern

Melvin Rubin called the Public Board Meeting to order at 9:08 a.m.

**1. Record of Conflict of Interest**

Melvin Rubin began the Public Session with the first order of business, asking if any Board member present had any conflicts of interest on any agenda item. For the record, there were no conflicts of interest pertaining to the June Public Agenda Items.

**2. Corrections to the Minutes – (05/19/04)**

*Page 1* – the spelling of last name under Guests should be changed from “Dyck” to “Dyke”; Under 3A, 3<sup>rd</sup> sentence, change “...has been appointed as one of the two representatives of Chain pharmacists representative for the same term.” to change “...has been appointed as one of the two Chain pharmacist representatives and will serve through April 30, 2008.”

*Page 5* – Under 8B, 1<sup>st</sup> sentence, change “...and gather information that is unclear during inspections.” to “...and provide feedback from the permit holder”

*Page 6* – 1<sup>st</sup> sentence, delete “is” following the word “Committee” and add a colon “:” after the word “question”; change “(2)... specific labeling individual dose...” to “(2)... specific labeling for individual unit dose...”; change “(3)...to service a LTVF. They...” to “(3)...to service a LTCF. There...”;

*Page 7* – under I. Board Action, add ‘,Legislative Officer,’ following James Slade’s name.

*Page 9* – Change adjournment time from “2:15 p.m.” to “12:15 p.m.”

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**Board Action**

Ray Love moved acceptance of the May 19, 2004 minutes as corrected. Mark Levi seconded the motion. The Board members unanimously supported the motion.

**3. President/Executive Committee Report – Melvin Rubin**

**A. New Board Members Welcome**

President Rubin welcomed newly appointed Board member, Donald W. Taylor, as the as Board Chain representative replacing Mr. Wayne Dyke.

**4. Executive Director Report – LaVerne Naesea**

- A. A response prepared, approved by the Board Executive Committee and submitted on June 8, 2004 to WBAL-TV (Dave Collins) was distributed to Board members. The television station had requested follow-up information regarding progress made by the Board in addressing recommendations of the 2001 Sunset Review Evaluation Report. Board member, Mark Levi mentioned that the request may have been made following a phone call he received from a consumer about a medication error complaint.
- B. Ms. Naesea noted the support letters and other correspondence included in the Board packets having been already approved by the Board prior to being sent. They included, a summary and support letter for an Office of Substance Abuse Studies DTM Project; Board comments related to the MD State Department of Education Health Services Guidelines; and a congratulatory letter sent in recognition of the Classes of 1954 and 2004 Pharmacy School Alumni Gala.
- C. Ms. Naesea indicated that the Board's Executive Committee had approved tentative plans for a three-phase reorganization of Board staff, and that the plan had been presented to and conceptually approved by Ms. Janet Nugent, Director of the Office of Human Resources for DHMH.
- D. Ms. Naesea indicated that she had submitted staff supports requests to DHMH. The Department approved the freeze exemption request to replace the Board Secretary and Temporary Clerk position. In addition, she noted that the selected candidate to replace the Personnel/Fiscal Officer had withdrawn her interest in the position.

**5. Guest Presenters: None**

**6. PEAC (Pharmacists Education and Assistance Committee)**

Mr. Gil Cohen announced that PEAC is presently working on 26 cases of which 12 are Board-referred. The Executive Director's position has not been filled however; PEAC is close to making a selection. PEAC is planning an August Retreat during which time training for four new monitors is planned. The Fall Continuing Education Program,

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entitled *Crossing the Line: When Prescription Drug Use Becomes Abuse and Addiction*, is scheduled on October 21, 2004.

PEAC's next meeting is scheduled for June 17, 2004.

**7. Regulations/Legislative Officer Report – James Slade**

**A. Pharmacy – Legislation Profile**

Mr. Slade noted the updated final legislative profile which was distributed at the meeting. He noted that the proposal for the Open Meetings Act (HB 73/SB 87), which would have allowed anyone to file a complaint in the circuit court for an alleged violation of the open meetings act, was vetoed for policy reasons. Also, regarding HB 433, the Prescription Drug Safety Act, the Department asked the Board whether it would need to prepare regulations. Board members indicated that the Board of Pharmacy would not need to prepare regulations for the proposal.

In discussing the Pharmacy Technician legislation that was sent for summer study, Mr. Slade, directed members to a letter from Chairman Hurson which was distributed during the Board meeting. Discussion ensued regarding how to proceed with the summer study that the Board had been asked by Chairman Hurson to initiate. The Practice Committee recommended that representatives from MACDS, NACDS, MHA, Kaiser Permanente, MSHP, Independent Pharmacy and ASCP be invited. The Board concurred with the recommendation and added MPhA. Mark Levi and Don Taylor were appointed to co-chair the workgroup and James Slade was assigned staff the Workgroup. The workgroup report is due to the legislature on December 1, 2004. Mr. Slade stated that he is still trying to coordinate schedules for the Drug Therapy Management committee meeting (Board of Pharmacy and MD Board of Physicians) representatives that will provide oversight).

James Slade asked members to begin thinking about legislative proposals they may want to support during the 2005 session. Members agreed that it wanted to support a statutory change that would allow consumer board members to be elected to officer positions on the Board.

The Board is to develop regulations for pharmacists to administer flu vaccinations, with the Board of Nursing and The Board of Physicians. Mel Rubin, Ray Love and Jeanne Furman will represent the Board on the committee and Ms. Emmaline Woodson and others will represent the Board of Nursing and the Board of Physicians. The Board recommended considering a non-member pharmacist with expertise in administration to also participate. Mr. Slade stated that the MBP is okay with receiving minutes of meetings, but wants a physician/pharmacist agreement because of concerns that a pharmacist may not be sufficiently prepared in patient assessment techniques, emergency procedures, and patient monitoring procedures.

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**Regulations Profile**

Mr. Slade noted the regulations profile in the Board Packets. He said that the proposed amendments to C.O.M.A.R.10.34.07, Pharmacy Equipment had been published in the *MD Register* with a 30 day comment period.

**9. Public Relations**

Ms. Joan Lawrence introduce Megan Dillard who joined the Board through the Governor's Summer Internship Program. She informed members that the FY 2003 Annual Report was in circulation and that the July 2004 newsletter would be ready for printing by the end of the week of the Board meeting.

**10. Pharmacy Practice Committee** – Since Committee Chair Ray Love was not in attendance at the most recent committee meeting, he asked Mr. Slade to summarize notes from the meeting.

**A. Question to the Board**

**Bar Code Packaging**

The Board approved a letter proposed by the committee in response to whether an automated system would still need to be checked by a pharmacist if bulk oral solids are loaded into the unit with bar code verification and the medication ordered for the patient is prepackaged and dispensed with a patient-identified strip and bar code on each package. Ray Love stated that in general terms, as long as a quality assurance system is in place a check under the scenario presented by the inquirer would not be required. The letter referred the inquirer to COMAR 10.34.28, and 10.34.28.04(A0(3)).

**Replacing Software for Automated Systems**

The committee proposed sending a letter in response to whether in replacing only the software of an automated dispensing system would require that the ADS restrict access to multiple dosage strengths, dosage forms or drug entities and other requirements of COMAR 10.34.28.04B. The letter stated that the Board felt that if there were no change in the hardware and the new software was in compliance with the pre-September 1, 2003 regulation requirements, then the ADS would be viewed as "old" ADS and therefore would only need to comply with the pre-September 1, 2004 requirements.

**Board Action** - Ray Love motioned, Ramona McCarthy-Hawkins seconded and the Board approved sending the letter.

**Automated Dispensing Systems (ADS) in Long Term Care Facilities (LTCF)**

The committee proposed sending a letter in response to questions regarding what type of authorization is required from the Board to use an ADS in a LTCF; whether the prescription requirements are different for items removed from an automated unit versus those dispensed directly to individuals in an outpatient setting; and whether the Board has issued requirements

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in order for a pharmacy to serve LTCF using ADSs. The inquirer specifically referred to proposed rules in the Federal Register, Vol. 68, No. 212 (Nov. 3, 2003) which would require state authorization for pharmacies to locate stock in ADS at LTCF and to ensure the transfer of controlled substances from the primary pharmacy to the LTCF site. The committee's letter indicated that only a pharmacy permit would be required to meet Board of Pharmacy requirements for use of an ADS in a LTCF, but said that the Office of Health Care Quality (OHCQ) has other requirements (COMAR 10.07.02.15) that may also need to be considered; the letter referred the inquirer to COMAR 10.34.23 and 10.34.28 for Board labeling medication requirements for LTCFs and also to OHCQ's regulation COMAR 10.07.02.15; and finally, the letter noted that the Division of Drug Control may also be a good reference to contact and suggested that the inquirer also review the Board's proposed revisions to COMAR 10.34.23 as published in the *Maryland Register* a couple of months earlier.

**Board Action** - Ray Love motioned, Don Taylor seconded and the Board approved sending the letter with minor amending.

**Prescriptions Generated by Computer and Faxed Without a Signature**

The committee proposed sending a letter in response to whether a prescription may be generated by a computer and faxed without a signature. The letter referred the inquirer to COMAR 10.34.20 and further stated that if a pharmacist is not satisfied that the requirements of this chapter of regulation are met, the pharmacists may refuse to fill the prescription.

**Board Action** - Ray Love motioned, John Balch seconded and the Board approved sending the letter.

**Holistic Substances**

The committee proposed sending a letter in response to an inquiry as to whether holistic substances constitute prescription or non-prescription drugs for the purpose of HO 12-101, et seq. statutory scheme; and whether information provided to patients about holistic substances constitute the practice of pharmacy by the physician, the pharmacist or the entity; The letter indicated that the pharmacist should review each substance to determine whether the substance is a prescription drug and referred the inquirer to MD. Code Ann., Health Occ. §12-101 (Supp. 2003) for Maryland's definition of prescription and non-prescription drugs. It noted that some of the items sold in holistic centers may be considered non-prescription drugs. Further the letter stated that if a licensed pharmacist is counseling patients regarding prescription or nonprescription drugs then the person is practicing pharmacy. It noted the difficulty in properly counseling patients regarding the interaction between prescription and non-prescription drugs and the fact that a person who counsels patients regarding interactions with prescription and non-prescription drugs must meet all requirements applicable to the practice of pharmacy since counseling of that nature is considered practicing pharmacy.

**Board Action** – Mark Levi motioned, John Balch seconded and the Board approved sending the letter.

**Pharmacy Technician Pharmacy Training**

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The committee proposed sending an e-mail in response to the MD Higher Education Commission's question about program criteria for pharmacy technicians. The letter stated that the Board does not currently have authority to regulate pharmacy technicians, but holds the pharmacist and permit holder responsible for technician's acts. It referred the inquirer to COMAR 10.34.21, described the 2004 pharmacist technician legislative proposal that was sent for summer study and offered to assist to help the MD Higher Education Commission as appropriate.

**Board Action** - Ray Love motioned, Ramona McCarthy-Hawkins seconded and the Board approved sending the letter.

**Expiration Date of Prescription Drugs**

The committee proposed sending a response to an inquiry from Linda Stahr, Principal Analyst for the Department of Legislative Services, regarding whether pharmacists can place expiration dates on prescription labels that may be earlier than the expiration date established by the manufacturer. The proposed response indicated that there may be patient safety reasons for the appropriateness of pharmacists practicing this. For example, once a container is opened or if the pharmacist is aware that the location where the prescription will be stored will quicken the medication's deterioration. The response cited the 2000 US Pharmacopoeia & National Formulary Official Compendia of Standard and provided examples of two medications (nitroglycerin tablets and antibiotics that require reconstitution) that may have accelerated deterioration under some circumstances.

**Board Action** - Ray Love motioned, Donald Taylor seconded and the Board approved the proposed response to Ms. Stahr.

**Insurance/PBM audits and Record Keeping**

Melvin Rubin proposed that the Board send a letter to Aetna and other PBMs and insurance companies regarding pharmacists being required to place refill information and prescribers' consents to increase refills on the back of original prescriptions forms and whether filled, non-dated prescriptions are legal. The letter referenced COMAR 10.19.03.07 and 10.34.08, and noted that both practices of entering documentation on the original order and of only entering documentation in the computer system are legal and meet the standards of practice for the profession. The letter further indicated that while the law requires a prescriber to date a prescription on the day it is written, the Board allows pharmacists to use professional discretion regarding whether to refuse to fill a prescription on that basis alone. If the pharmacist determines that the prescription is not too old to be filled (within 120 days), that the date and other required information is attached by means of a computer generated strip, and that the prescription is appropriate, then the Board considers the intent of the law to have been satisfied. Board members' discussions also noted that prescriptions must be kept in a readily retrievable form for five years.

**Board Action** – Don Taylor motioned, Ramona Hawkins seconded and the Board approved the proposed letter to Aetna.

**B. Post-Inspection Survey Form**

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Melvin Rubin reported meeting with Mr. Jack Freedman of the Division of Drug Control who was not satisfied with the post-inspection survey developed by the Board. The Practice Committee will take his concerns under consideration, make appropriate adjustments to the survey and then it will be distributed to permit holders.

**C. Long Term Care Task Force**

The Long Term Care Task Force met with the Office of Health Care Quality (OHCQ) on June 9, 2004, at which time the methods that pharmacists dispensed medications were discussed. OHCQ Director, Carol Benner suggested that the Board meet with Life Span regarding the lack of coordination in requesting refills. It was noted that many refills are generated from open-ended prescription orders where the physician has not performed follow-up examinations of the patients. Board members determined that open-ended prescriptions in LTC facilities should be addressed through regulations and delegated the Practice Committee to determine the conditions under which such orders would be acceptable. Mel Rubin, Mayer Handelman and Johan Balch will meet with Life Span representatives to discuss that and other concerns. Following an extensive discussion, Regulations/Legislative Officer, James Slade was directed to investigate how other states have addressed the problem. ASCP was recommended as a resource for his research.

**11. Licensing Committee**

**Multi-state Pharmacists Jurisprudence Examination (MPJE) Review Committee**

Melvin Rubin reported that former Compliance Officer, Michelle Andoll, and he were representatives on the National Association of Boards of Pharmacy's (NABP) Multi-state Pharmacists Jurisprudence Examination (MPJE) Review Committee. He indicated that he plans to apply for another three-year term appointment.

**Board Action** – John Balch motioned, Jeanne Furman seconded and the Board voted to support Melvin Rubin's application to be appointed to a second three-year term. .

**Pre-Inspection Forms**

A draft of the revised Pre-inspection Form was distributed to members along with a letter regarding what would be required during the time of the actual inspections. Board members approved the documents with minor corrections.

**Request from National Institutes of Health**

Melvin Rubin distributed an e-mail request from the NIH along with his proposed response. The inquirer wanted to know whether US Public Health Service pharmacist-officers would be able to participate in HHS clinic emergency-preparedness drills and trainings in Montgomery County, MD without have a MD pharmacist license. Assistant Attorney General, Linda Bethman advised that their participation would not be a problem in Maryland as long as they would not actually be dispensing drugs during the trainings.

**12. Emergency Preparedness Committee**

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Joan Lawrence noted that the statewide drill took place earlier in June. She asked Melvin Rubin to provide a report. Mr. Rubin indicated that former Board President Stanton Ades was telephoned at midnight regarding an “Anthrax cloud” that had been released over Camden Yards. He said that eventually he received the request for support around 6:00 a.m. on the following morning. He said that counties were instructed to individually notify DHMH about the number of people affected in their areas, the number pharmacists needed, and other related information. Mr. Rubin said that a summary of the drill and its problems and successes will be provided to DHMH at its next meeting.

The Public Board session adjourned at 11:55 a.m.

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